# Table of Contents

Hepatitis 'C' Status File	2
Input Files	2
Variables	2
Updating the File	3
HCV Genotype/Simmonds' Analysis File	3
File	3
Duplicate records issue	3
About Simmonds' HGV Data	3
About the genotypes	3
About the recoding.	3
Variables	4
Comments about the variables on the file	5
Group and Genotype Combinatins	6
Input Files and DATE STAMP issues	7
Updating the File	7
HCV Birth Cohort File (Combined File)	8
About the file	8
Variables	8
Updating the file	9
**** One time update	9
Analysis File for 01/99 Publication	10

Create program	10
About the file	10
Input files	10
Variables	10
PDS of Mainframe programs	11
Other Files	12
LABDATA	12
LIVER	12
RIBA	12
RIBAT4T8	13
TCELLS	13
Dr. Eyster's Analysis for JID paper 09/98	14
About the file	14
Input Files	14
Variables	14
Updating the file	15
HCV Serotyping File	15
About the file	15
Input Files	16
Updating the file	16
First Hepatitis C Sub-Genotype File	16
Issues and Recodes	17
Variables:	17

HGV Couples Analysis Files	18
About the files	18
Input files	18
Variables on Subject File	19
Variables on Spouse Pair File	20
Updating the Files	21

# Hepatitis 'C' Status File

This file contains one record per subject and their hepatitis C status. This is the SUBJECT'S overall status, based on laboratory information.

NTT1SWY.CS5.HCVSTAT.SASDS(.STAT)

\*\*\* One record per subject, sorted by SUBJ\_ID.

# **Input Files**

UAT1PIV.HIV9.HEP.SASDS (.SCREEN) & (.BLOT)

# Variables

SUBJ\_ID - Subject Id Number HCV STAT - Overall status

TEST - Type of Hepatitis C test used

HCV\_STAT is set as follows using PCR/RIBA and screen results: Only the '+' PCR results are considered

PCR	RIBA2RIBA3 HCV Sta		<b>HCV Status</b>	itus	
+	any	an	ıy	+	
	+	-		+	
+		/		+	
	+	+		+	
	-	_		_	
	-	/		/	
	-	+		+	
	/	_		_	
	/	/		/	
	/	+		+	

If no PCR or RIBA was done, the subject takes the status from the screen result. If the screens conflict the status is '/'.

# **Updating the File**

Run from NTT1SWY.CS5.HCV.SAS(CRESTAT)

# HCV Genotype/Simmonds' Analysis File

# File NTT1SWY.CS5.HCVGENOS.SSD(.HCV) C:\hemfiles\allgeno.sd2

# **Duplicate records issue**

The file was originally designed to have one record per subject

Dr. Eyester's original data was added and contained paired samples - which created duplicates for subjects sometimes with conflicting genotype results

.

These duplicate samples must be handled by the specs of individual analysis.

#### **About Simmonds' HGV Data**

The RFLP data from Dr. Simmonds also contained an HGV flag. Since the only HGV data we maintain is the HGV Couples File which will be analyzed as a unit, Dr. Simmond's HGV data will temporatily be kept here.

# **About the genotypes**

This file contains the HCV genotype results from Dr. Hatzakis at the Hemophilia Center in Athens. The genotypes come in as text and reflect combinations of genotypes 1-5, Positive NOS, or Negative. It also contains 110 HCV RFLP results from Dr. Simmonds in Scotland. 42 of these were sent directly from Dr. Eyster. These 42 records will not have genotype information unless by chance.

An few examples are these;

1a - A clean genotyping of 1a

1a, 1b - A mixture of genotype 1; that is 1a AND genotype 1b detected 1, 1a - A different mixture: that is '1' (not genotyped further) AND 1a

2a/2c - EITHER 2a OR 2c detected

1a, 2a/2c, 4 Genotype 1a, EITHER 2a or 2c, AND Genotype 4

.

# About the recoding

They are recoded 2 ways for analysis

The 'ANY' flags ANY1-ANY5 (for genotypes 1-5) ANY0 (negative) and ANY9 (positive NOS) are set independently of each other. For example, genotype '1a, 4c/4d' will turn on ANY1, and ANY4...

The grouping variable 'GROUP', however, is set as a hierarchy in the following order.

```
1 = More than 1 genotype (ie 1a, 4c)

2 = Negative

3 = Positive - not otherwise specified

4 = Any 1 (for example genotype '1' or genotype '1, 1a')

5 = Any 2 " for genotype 2

6 = Any 3 " for genotype 3

7 = Any 4 " for genotype 4
```

8 = Any 5 " for genotype 5

When Jim talks about 'ANY1' for example, he is referring to the hierarchy of variable GROUP. The ANY flags are just internal to the file for coding and checking purposes..

#### Variables Genotype result is 'NEGATIVE' ANY0 ANY1 At least 1 Genotype 1 At least 1 Genotype 2 ANY2 At least 1 Genotype 3 ANY3 At least 1 Genotype 4 ANY4 ANY5 -At least 1 Genotype 5 ANY9 Genotype result is POSITIVE but UNSPECIFIED BIRTH Birth date (SAS) 1 = 1900 - 19492 = 1950 - 19543 = 1955 - 19594 = 1960-19645 = 1965 - 19696 = 1970 - 19747 = 1975 - 19798 = 1980 - 19849 = 1985 - 1996US or European country COUNTRY -Draw date of genotyped sample - SAS DRAW DT STAMP -Date the GENOTYPE data was received - (SAS) records with RFLP results only have a missing date stamp GENOTYPE -Genotype **GROUP** Genotype group 1 = More than 1 genotype2 = Negative3 = Positive - not otherwise specified 4 = Any 15 = Any 26 = Any 37 = Any 4

8 = Any 5

GROUPTXT - Probably silly to include, but comes in handy in printouts

More than 1

Neg '+' NOS ANY 1 ANY 2 ANY 3 ANY 4 ANY 5

HCV STAT - HCV Status at time of selection for genotyping

HGVMAT - Material code of Simmond's HGV results

LIVERDT - Liver Disease Dx date - SAS

LIVFLAG - Liver Disease flag 0/1/2 (neg/pos/possible)

RFLP - RFLP result from Dr. Simmonds

SAMPL\_ID - Sample Id

SIMMHGV - Simmond's HGV result

STATANL - HIV Status at time of selection for genotyping

SUBJ ID - Subject Id

#### Comments about the variables on the file

The US subjects selected to be genotyped were chosen by **HCV status** (all positive), their **HIV status** (approximately 1/2 and 1/2) and **birthyear** (cross section) at the time of selection. The Greeks that Dr. Hatzakis selected were all HIV positive, all HCV positive (by his own test) and not selected by birth year. 5 Greek subjects were HCV neg/equiv by our test. In order to match analysis already performed, the HIV, HCV status flags and birth year were kept on the file. The danger, of course is that these could change by data correction or more tests, so the changable nature of these variables must be kept in mind.

All of the Greek subjects are in the MHCS study. However the results on 25 Greek subjects were on **Subject Id/Draw Date combinations** that are not in our background file. Dr. Hatzakis only provided the subject Id and date, therefore the Sample Id on these records is missing. A report to this effect was sent to him and he verified the dates. This has already resulted in analysis problems when the draw dates were later than our LKA. Dr. Hatzakis has given us updated LKA's and AIDS status. This will be incorporated into our permanent files.

# Group and Genotype Combinatins

GROUP	GROUPTXT	GENOTYPE
1	More than 1	1, 1a, 2a/2c, 2b

			1,2,3 1a, 2a/2c 1a, 2a/2c, 1a, 2b 1a, 4c/4d 1b, 2b 1b, 3a 3a, 2b 4c/4d, 1a
2	Neg		Neg
3	'+' NOS		Pos NOS
4	ANY 1	1	1, 1a 1, 1a, 1b 1a 1a, 1b 1b 1c/1d
5	ANY 2	2a	2a,2b 2a/2c 2a/2c, 2b 2b
6	ANY 3	3a	3a,3b
7	ANY 4		4a 4c/4d
8	ANY 5	5a	

4

# **Input Files and DATE STAMP issues**

# 1. NTT1SWY.CS5.HCVSUB.GENO0197.SSD

Hershey only DATE STAMP - 1/1/97 n=58

The create program is &NTT1SWY.HCV.GENO98.SAS(MAKE0197) and c:\hcv\hcvsas\make0197 see the following section entitled **First Hepatitis Sub-Genotype File** for details of this data.l

#### 2. NTT1SWY.CS5.HCVSUB.GENO0797.SSD

All U.S. subjects.

Large group from Dr. Hatzakis is the core subjects of the 'HCV Combined file DATE STAMP - 7/1/97 n=320

The create program is lost - but information about the input files is in program &NTT1SWY.HCV.GENO97.SAS(MAKEFILE)

# 3. NTT1SWY.CS5.HCVSUB.GENO0198.SSD

Additional results from Dr. Hatzakis. Greeks only.

DATE STAMP - 1/1/98 n=129

The create program is &NTT1SWY.HCV.GENO98.SAS(MAKE0198) and c:\hcv\hcvsas\make0198

#### 4. NTT1SWY.HCV.SIMMONDS.RFLP.L26

The data was created from diskette of results

DATE STAMP - MISSING on results sent direction from Dr. Eyster n=42

#### 5. NTT1SWY.CS5.HCVSUB.GENO0998.SSD

All Hershey subjects

New and old data from Hershey. Replaces the previously received data. DATE STAMP - 9/11/98 on completely new records. File contains new data, duplicates of old data, and updated data on previously existing subject/draws. Create program is saved as c:\hcv\hcvsas\make0998.sas and &NTT1SWY.HCV.GENO98.SAS(MAKE0998)

#### 6. NTT1SWY.CS5.HCVSUB.GENO1298.SSD

New data from Dr. Hatzakis

**DATE STAMP - 12/01/98** 

Create program is saved as c:\hcv\hcvsas\make1298.sas and &NTT1SWY.HCV.GENO98.SAS(MAKE1298)

**Updating the File** Run from NTT1SWY.HCV.GENO98.SAS(CREANAL).

#### **HCV Birth Cohort File (Combined File)**

(Combined Genotype/Serotype/bDNA File File NTT1SWY.HCV.COMBINED.

NTT1SWY.HCV.COMBINED.SSD(.HCV)
C:\hemfiles\hcvcomb.sd2

One record per sample, sorted by sample

#### About the file

310 of the samples genotyped at one time by Dr. Hatzakis (date stamped 070197 on the genotype file) were selected to be tested by all three HCV PCR tests; Bdna, genotype and serotype (Chiron test at SAIC). When necessary, due to shortage of blood, the samples closest to the genotyped sample was chosen and tested. The 'HAS' flags refer to the presence of test results - not whether or not the results are on the same sample. The time variables can be used to select results based on some specified minimum time from genotype draw dates.

Input Files NTT1SWY.CS5.HCVGENOS.SSD(.HCV) UAT1PIV.HIV9.PCR.SASDS(.PCR)

Variables: \* see notes in HCV Genotype/Simmonds Analysis File

AGEDRAW - Age at draw
AIDS - AIDS flag
ANY0 \* - Genotype Neg

ANY1 \* - Any 1 ANY2 \* - Any 2 ANY3 \* - Any 3 ANY4 \* - Any 4 ANY5 \* - Any 5 ANY9 \* - Pos/NOS

BDNA - HCV bDNA viral load

BDNACAT - HCV bDNA category (0-3 neg-high)

BIRTH - Birth date - SAS
BRTHYR - Birth year category
CNTL1 - Control Band 1
CNTL2 - Control Band 2
CORE1 - Core1 Band4
CORE2 - Core2 Band5

COUNTRY - Country

DAIDS - AIDS date - SAS

DILUTION - Dilution

DRAW - Draw Date - SAS DT DEATH - Death date mmddyy

GENOTYPE - Genotype

GROUP - Genotype Group #
GROUPTXT - Genotype Group Name

LFLAG - Liver Disease flag 0/1/2 (neg/pos/possible)

LIVERDT - Liver Disease Dx date - SAS

LIVSURV - Liver Survival - Startdt --> LIVERDT

LKA - Last Known Alive - SAS

NS41 - NS4 Band1 NS42 - NS4 Band2 NS43 - NS4 Band3

RFLP - RFLP - Dr. Simmonds, Scotland SERODT - Seroconversion date - SAS

SEROTYP - Chiron Serotype

STARTDT - Later of 5/29/82 or birth - SAS

STATANL - HIV Status SUBJ ID - Subject Id

SURVIVAL - STARTDT - LKA

VITLSTAT - Vital Status 1/2 (alive/dead)

# Updating the file

Run c:\hcv\hcvsas\combine.sas - it creates and uploads the file Program also saved as &NTT1SWY.HCV.GENO98.SAS(COMBINE)

# \*\*\*\* One time update

The file has been modified one time since its creation. In January 1999, 3 subjects had HCV serotypings successfully refined.

The program used is saved as c:\hcv\hcvsas\combupdt.sas and &NTT1SWY.HCV.GENO98.SAS(COMBUPDT)

# Analysis File for 01/99 Publication

# File NTT1SWY.HCV.PAPER99.SSD(.HCV)

C:\HCV\PAPER99\PAPER99.SD2

One record per subject, sorted by subject

# Create program

&NTT1SWY.HCV.PAPER99.SAS(CREANAL)
C:\HCV\PAPER99\CREANAL.SAS

About the file

This file is the analysis file that will be frozen and used for 01/99 analysis done for publication. It contains 1192 HIV positive and 624 HIV negative subjects for a total of 1816 subjects. All are HCV positive .It uses the updated DEC98 liver disease file, and only second generation Bdna results (RSLT\_TYP 'C2'). The subjects are divided into 3 groups:

\*\*\* 1 Birth Cohort - the 310 subjects in the birth cohort (combined) file

- Plus Cases 38 liver disease cases that, like the birth cohort file have bdna, serotyping and genotyping on the same sample
- 3 Every one else

# **Input files**

NTT1SWY.CS5.ANALSYIS.SASDS (.HEMOPH)
NTT1SWY.CS5.RTI.ORI.VARS.SASDS(.HEMPH)
NTT1SWY.CS5.LIVER.DEC98.SSD(.HEMOPH)
NTT1SWY.CS5.HCVGENOS.SSD(.HCV)
NTT1SWY.HCV.COMBINED.SSD(.HCV)
NTT1SWY.CS5.SEROTYP.SSD(.SERO)
UAT1PIV.HIV9.PCR.SASDS(.PCR)

#### Variables

AGE0 - Age at start date

AGE3 - Age0 in terciles (values 1-3) AGE5 - Age0 in quintiles (values 1-5)

BDNA - bdna value chosen

BIRTH - Birth date (SAS)

CENSORDT - Earlier of Liver Disease, LKA, 5/28/98

used in all analysis with Liver Disease as outcome

CNTL1 - Serotype band

CNTL2 - Serotype band
CORE1 - Serotype band
CORE2 - Serotype band

DEAD - Death flag 0/1

ENDDATE - Earlier of LKA, 5/28/98

used in all analysis with Death as outcome

F BDNA - Subjects 1<sup>st</sup> bDNA count - for subjects with 2+ bDNA's

F DATE - Date of subjects 1<sup>st</sup> bDNA count

GENOTYPE - HCV genotype

GROUP - Birth cohort/plus/everyone else \*\*\*\*

ISFROM - 'US' or 'EU'

L BDNA - Subject's last Bdna count - for subjects with 2+ bDNA's

L DATE - Date of subject's last bDNA count

LASTFRST - log10 of last bdna minus log10 of first bdna

LINKCD4 - CD4 count closest to the 'linked' draw date for subjects with bdna,

serotyping and genotyping on same 'linked' sample

LINKCD8 - CD8 count closest to the 'linked' draw date for subjects with bdna,

serotyping and genotyping on same 'linked' sample

LIVER- Liver disease 0/1

LIVERDT - Liver disease diagnosis date (SAS)

LKA - Last known alive (SAS)

NEWTYP - Hemophilia type (see AIDS file documentation)

NS41 - Serotype band NS42 - Serotype band NS43 - Serotype band

SAMPDRAW Draw date for samples with bdna and geno/serotypes. ie: "linked sample

SEROTYP - Selected HCV serotype SEV - Hemophilia Severity

STARTCD4 - CD4 count closest to start date STARTCD8 - CD8 count closest to start date

STARTDT - Start date. Later of 5/19/82 or birth (SAS)

STATANL - HIV Status

STCD4\_DT - Date of 'STARTCD4' (see above)
STCD8 DT - Date of 'STARTCD8' (see above)

STUDY\_ID - Study Id SUBJ ID - Subject Id

#### PDS of Mainframe programs

#### NTT1SWY.HCV.PAPER99.SAS

Contains all the programs written for and run on the mainframe (Kaplan Meires ect.)

'CREANAL' - copy of the program that created the analysis file

#### **Other Files**

There are 5 files in &NTT1SWY.HCV.PAPER99.SSD in addition to the analysis file "HCV"

#### LABDATA

&NTT1SWY.HCV.PAPER99.SSD(.LABDATA)
C:\HCV\PAPER99\LABDATA.SD2

Contains laboratory and clinical information (such as alcohol) on the subjects

Programs to create file &NTT1SWY.HCV.PAPER99.SAS(CRELAB) c:\hcv\paper99\CRELAB.SAS

This program did not write to the PAPER99 PDS. The day after Fran created the file 1/27/99, 1/28/99 it was copied onto

#### **LIVER**

&NTT1SWY.HCV.PAPER99.SSD(.LIVER) C:\HCV\PAPER99\NEWLIVER.SD2

Created by Fran Yellin's program and copied into the paper99 PDS and directory at the time of analysis 1/99

#### **RIBA**

&NTTISWY.HCV.PAPER99.SSD(.RIBA) C:\HCV\PAPER99\RIBA.SD2

Contains the RIBA data used in this analysis. Uses the RIBA results closest to the subject's STARTDT.

Program to create the file is lost

#### RIBAT4T8

&NTT1SWY.HCV.PAPER99.SSD(.RIBAT4T8)

# C:\HCV\PAPER99\RIBAT4T8.SD2 RIBA related CD4 and CD8 data

Program NTT1SWY.HCV.PAPER99.SSD(RIBAT4T8)

C:\HCV\PAPER99\RIBAT4T8.SAS

Contains the draw date of the RIBA used in analyis, and the draw dates and CD4/CD8 counts and percentages of the CD4/CD8 closest to RIBA

#### Variables

RIBADRAW - Draw date of RIBA

RIBANT4 - CD4 count closest to RIBA
RIBANT8 - CD8 count closest to RIBA
RIBAPT4 - CD4 % closest to RIBA
RIBAPT8 - CD8 % closest to RIBA

SUBJ ID - Subject Id

T4DRAW - Draw date of CD4
T8DRAW - Draw date of CD8

TOCD4 - Time from CD4 to RIBA
TOCD8 - Time from CD8 to RIBA

#### **TCELLS**

NTT1SWY.HCV.PAPER99.SSD(.TCELLS) C:\HCV\PAPER99\TCELLS.SD2

The T-Cell file as it existed when analysis was begun 1/20/99 - all records for the hemophiliacs with either a CD4 or CD8 result

# Dr. Eyster's Analysis for JID paper 09/98

# File NTT1SWY.HCV.EYSTANAL.SSD(.HCV)

c:\hcv\hemfiles\eystanal.sd2

One record per subject/draw date, sorted by subject/draw

#### About the file

In September 1998 Dr. Eyster submitted a paper on the original genotype analysis she had done, on the 17/17 HIV+HIV- subjects she has been following for years. We have complete data on

16 pairs, so only 32 subjects were included in the analysis. Her analysis used both data from the 'original' HCV genotypes (date stamp 1/1/97) on the genotype file, and some additional data from Dr. Hatzakis that was new to us, but not to her.

A file was created containing the data used for this analysis. Two subject/draw dates have different genotypes on this file and the genotype analysis file. HER040 (01/08/86), and HER243 (12/17/86) were tested twice. The genotypes on this file reflect the first results that came in on them in 1997 since all her analysis is based on a batch being tested as a unit.

# Input Files c:\hcv\hemfiles\allbdna.sd2 (NTT1SWY.CS5.HCVGENOS.SSD(.HCV)

C:\hcv\eyster\dataused.dat

(NTT1SWY.HCV.EYSTER.LINKUP.DAT)

T 7	-	•		
•	ar	10	h	les
•	aı	14	W.	

ANY0 - Genotype result is 'NEGATIVE'

ANY1 - At least 1 Genotype 1 ANY2 - At least 1 Genotype 2 ANY3 - At least 1 Genotype 3 ANY4 - At least 1 Genotype 4

ANY5 - At least 1 Genotype 5

ANY9 - Genotype result is POSITIVE but UNSPECIFIED

DRAW - Draw date (SAS)

GENOTYPE - Genotype

GROUP - Genotype group

1 = More than 1 genotype

2 = Negative

3 = Positive - not otherwise specified

4 = Any 1

5 = Any 2

6 = Any 3

7 = Any 4

8 = Any 5

GROUPTXT - Probably silly to include, but comes in handy in printouts

More than 1

Neg

'+' NOS

ANY 1

ANY 2

ANY 3 ANY 4

ANY 5

HCV STAT - HCV Status at time of analysis

LIVFLAG - Liver Disease Flag

LIVERDT - Liver Failure Date (SAS)

PTNUM - Patient number Dr. Eyster uses to identify subjects

RFLP - RFLP result from Dr. Simmonds

STATANL - HIV Status

\*\*\*\*\*\*\* HER DRAW DATES ARE OFTEN OFF BY A DAY OR SO. This was attempted to be cleaned up, but the two close-in-time draw dates are often both on the background file with different sample id's. There is no pattern of which ones contains the RFLP and/or Bdna results. Therefore, any additional data on these subjects will have to be looked at carefully before analysis.

# Updating the file

Run c:\hcv\hcvsas\eystanal.sas - it creates and uploads the file Program also saved as &NTT1SWY.HCV.EYSTER.SAS(CREANAL)

# **HCV Serotyping File**

# File NTT1SWY.HCV.SEROTYP.SSD(.SERO)

One record per sample, sorted by sample.

# About the file

This file contains the results from the Chiron Serotying performed at SAIC. The valid results sent from the lab consist of serotypes '1', '2',or '3', serotype 1 or 3 read as '13', and two additional codes 'UTY' and 'DIL' which stand for 'untypable' samples, and the recommodation to 'DILUTE' the sample and test again.

The program does the following. The controls are deleted. The following hierarchy is applied to the dilution results: 33, 132, 660 and 10, UTY, DIL - with 33 being the preferred dilution. One record per sample is put out. Samples that only have result/results of 'UTI' have serotype changed to 'WEAK'.

# **Input Files** UAT1PIV.HCVSER.SSD(.SERO)

Variables		
CNTL1	-	Cntrl 1
CNTL2	-	Cntrl 2
CORE1	-	Core1 Ba

CORE1 - Core1 Band4 CORE2 - Core2 Band5 DILUTION - Dilution

DRAW - Draw date (SAS)

NS41 - NS4 Band1 NS42 - NS4 Band2 NS43 - NS4 Band3 SAMPL\_ID - Sample Id SEROTYP - Sero Type SUBJ ID - Subject Id

WANTDIL - Dilution ranking (see 'About the File)

# Updating the file

Run c:\hcv\hcvsas\cresero.sas - it created and uploads the file Program also saved as &NTT1SWY.CS5.HCV.SUBTYPE.SAS(CREATE)

# First Hepatitis C Sub-Genotype File

Analysis File: NTT1SWY.CS5.HCV.SUBTYPE.SASDS

Input Files: NTT1SWY.CS5.LVRRNA.MEAN.APR94

NTT1SWY.CS5.LIVERDIS.SUBTYPE.L42

Create Program: NTT1SWY.CS5.HCV.SUBTYPE.SAS(CREATE)

Dr. Hatzakis was sent samples for HCV subtypings testings. The results were put in a flat file NTT1SWY.CS5.LIVERDIS.SUBTYPE.L42. The following documatation is describing the SAS date created from this. This file contains all the variables that have been used for the preliminary analysis. The sample XA 2473 has had the draw date in the Liver Disease File (CS5.LVRRNA.MEAN.APR94) corrected to match the background file.

#### **Issues and Recodes**

- A. Several formats of the HCVRNA levels are included.
  - 1. HCVRNA A is the adjusted RNA level (RNA\*0.073)
  - 2. RNAMULT is the adjusted RNA value multiplied by a factor based on the corresponding subtype: If the subtype is one of the '2's the HCVRNA\_A is multiplied by 3. If the subtype is one of the '3's the HCVRNA A is multipled by

- B. The pos/neg PCR\_EYE variable used for the original Liver Disease analysis for Dr. Eyster is included.
- C. The subtyping variables based on draw date filled in and a variable that reflects the change in a subject's subtyping over time is created. The following rules apply.
  - 1. Sub1, sub2, sub3 are filled in based on the draw date of the subtyping, even if some of the samples selected did not get tested; Therefore a person could have sub2 filled in with sub1 blank.
  - 2. The subtype results 'missing' and 'NEG' are ignored in the creation of the 'change over time' variable.

The 'change over time' values consist of changes from and to '1A' and '3A'. The values at this time are:

1A --> No Later
1A --> Other
1A --> 1A
3A --> NO LATER
3A --> OTHER
3A --> 3A
OTHER --> DIFFER
OTHER --> NO LATER
NO RESULTS

#### Variables:

CATS9	Char 20	Subtype Change
DRAW	Numeric	Draw Date (SAS)
HCVRNA	Numeric	Orig HCVRNA Level
HCVRNA_A	Numeric	HCVRNA * 0.073
PCR_EYS	Numeric	0/1 PCR Flag - Dr. Eyster
RNAMULT	Numeric	Adjusted * 2 or 3
SAMPL_ID	Char 7	Sample
SUB1	Char 5	Result of first draw sent
SUB2	Char 5	Result of second draw sent
SUB3	Char 5	Result of third draw sent
SUBJ_ID	Char 11	Subject
SUBTYPE	Char 5	Subtype

<sup>\*\*\*</sup> The trend of OTHER --> SAME did not occur, but could with more results.

#### **HGV Couples Analysis Files**

#### About the files

706 samples from 353 spouse pairs were sent to Dr. Harvey Alter's lab for PCR and antibody testing. We have received 405 (406?) results.

The antibody flag sent from the lab is generally based on the premise that a cutoff over 0.85 is positive. There are however three samples with a cutoff over 0.85 and the antibody 0. This was done at the lab on purpose because of evidence that it was a false positive. Two new antibody flags were created for the data. High Antibody Flag is set if the cutoff is > 1.02. Low Antibody Flag is set if the cutoff is > 0.75.

# &NTT1SWY.HGV.ANALYSIS.SASDS(.HCG)

SUBJECT FILE One record per sample (subject) 706 records - but not all have been tested for HGV If tested the HGVSTAT will not be missing

#### &NTT1SWY.HGV.FEMHEM.SSD(.HGV)

SPOUSE PAIR FILE One record per spouse pair 353 records - but not all have been tested If female has been tested FEMRSLT will equal 1 If male has been tested HEMRSLT will equal 1

# **Input files**

NTT1SWY.CS5.TOHGV.PLASMA.D0297 C:\HGV\PSENT.DAT Plasma samples sent for testing

&NTT1SWY.CS5.TOHGV.SERUM.D0297 C:\HGV\SSENT.DAT Serum samples sent for testing

&NTT1SWY.HGV.PLASMA.DAT.L23 C:\HGV\PLASMA.DAT Only plasma samples with test results

&NTT1SWY.HGV.SERUM.DAT.L23 C:\HGV\SERUM.DAT Only serum samples with test results

&NTT1SWY.CS5.ANALSYIS.SASDS(.HEMOPH) &NTT1SWY.CS5.HCVSTAT.SASDS(.STAT)

# Variables on Subject File

AGE Age at draw BIRTH Birthdate (SAS)

COMBSTAT Flag combination (see variable note \*\*)
CUTOFF Laboratory cutoff. > .85 consirderd positive

DRAW Draw date (SAS)

DT\_STAMP File Date - date result put in the file

FAMILY Family Code HCV\_STAT HCV status

HGVAB HGV Antibody flag HGVSTAT Overall HGV Status

HIGHAB Flag indicating cutoff > 1.02

INHIB Inhib

LABNUM Lab #

LOWAB Flag indicating cutoff > .75 MAT CODE Material B1-Serum, B2 Plasma

OD Laboratory OD PCR HGV PCR flag

SAMPL\_ID Sample SEX Sex

STATANL HIV Status
SUBJ\_ID Subject
TITER log10 Titer of RNA

#### Variable note \*\*

The 'combination flags' show which one (if any) of the HGV results - PCR and antibody are positive. The variable contents are 'AB', 'PCR', 'BOTH', 'NONE'. 'NONE' means that we have an antibody and PCR result and they are both negative. These flags are not set to 'NONE' to indicated missing data.

# Variables on Spouse Pair File

FAMILY Family code - matching to SUBJECT FILE

FEMAB Female partner antibody flag
FEMAGE Female partner age at draw
FEMBIRTH Female partner birthdate (SAS)

FEMCOMB Female partner flag combination (see variable note \*\*)

FEMHCV Female partner HCV Status

FEMHIGH Female partner High Ab > 1.02

FEMHIV Female partner HIV FEMID Female partner Id

FEMLOW Female partner Low Ab > .75
FEMMAT Female partner Material
FEMPCR Female partner PCR flag

FEMRSLT Female has result

FEMSAMP
FEMSEX
Female partner Sample
FEMSEX
Female partner HGV titer
FGSTAT
Female partner HGV
HEMAB
HEMAGE
HEMBIRTH
Hem antibody flag
Hem age at draw
Hem birth date (SAS)

HEMCOMB Hem flag combination (see variable note \*\*)

HEMHCV Hem HCV status

HEMHIGH Hem High antibody flag 1.02

HEMHIV Hem HIV Status

HEMID Hem Id

HEMLOW Hem Low Ab > .75
HEMMAT Hem Material
HEMPCR Hem PCR
HEMRSLT Has Result
HEMSAMP Hem Sample
HEMSEX Hem Sex

HEMTITER Hem HGV titer
HIVPAIR HIV Pair Status
MFPAIR HGV Pair Status
MGSTAT Hem HGV Status

# **Updating the Files**

C:\HGV\CREANAL.SAS &NTT1SWY.CS5.HGV.SAS(CREANAL)